

REMARKS**Acknowledgement of Receipt of Request For Continued Examination**

Applicant appreciates the Examiner's acknowledgement of its timely filed Request for Continued Examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e).

Additionally, Applicant also appreciates the Examiner's acknowledgement of the Examiner's withdrawal of the finality of the previous Office Action pursuant to 37 C.F.R. 1.114 in light of the fee per 37 C.F.R. 1.117(e) being paid. Lastly, Applicant also appreciates the Examiner's entrance of its submission filed on August 3, 2009.

Status of the Claims

Applicant appreciates the Examiner's acknowledgement that claims 1, 12 and 37 were previously amended and that claims 5, 13-36, 42, 51 and 58 were cancelled. Such amendments and cancellations were without prejudice or disclaimer of the subject matter thereof. Presently, claims 1-4, 6-12, 37-41, 43-50, 52-57 and 59-60 are currently pending in this application and are subject to rejection.

Rejection of Claims 1-4, 6-12, 37-41, 43-50, 52-57 and 59-60 under 35 U.S.C. 103(a)

The Examiner has maintained a rejection of claims 1-4, 6-12, 37-41, 43-50, 52-57 and 59-60 under 35 U.S.C. 103(a) as being unpatentable over Casswall et al. (Bovine Anti-Helicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) in view of Burggraber et al. Bruggraber et al. (U.S. Patent Application 2003/0180381 A1, Published 09/25/2003) and as evidenced by Dial et al. (Antibiotic Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998).

Applicant again respectfully asserts that in order for an Examiner to establish a prima facie case of obviousness, the Examiner must show that each and every one of the claim limitations was

suggested or taught by the prior art being relied upon. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, “[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). When an independent claim is deemed nonobvious under 35 U.S.C. 103, then all claims depending therefrom are nonobvious as well. *In re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

Additionally, Applicant again asserts that to support an obviousness rejection, MPEP §2143.03 requires, “all words of a claim to be considered” and MPEP §2141.02 requires consideration of both the, “invention and the prior art reference as a whole.” The Board of Patent Appeal and Interferences also recently confirmed that a proper, post-KSR obviousness determination still requires the Office to make a, “searching comparison of the claimed invention – including all its limitations – with the teachings of the prior art.” *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Ochiai* 71 F.3d 1565, 1572 (Fed. Cir. 1995) and *CFMT v. Yieldup Intern. Corp.* 349 F.3d 1333, 1342 (Fed. Cir. 2003). As such, it is a well-settled principal in the law that an obviousness rejection requires the Examiner to address all elements in a rejected claim.

Applicant respectfully asserts that none of the references teach or suggest that a mucolytic agent like N-acetyl cysteine would enhance the anti-bacterial nature of hyperimmune colostrums or hyperimmune milk. In contrast, Bruggraber et al. teaches the use of a mucolytic agent, such as acetylestine, to facilitate targeting to the mucous layer and in no way does this reference teach or suggest the use of a mucolytic agent for reduction of bacterial colonization.

In support of this position, Applicant herein respectfully submits the attached Declaration pursuant to 37 C.F.R. § 1.131 by one of the inventors, Dr. Cuong Tran of Children of Youth and Women’s Health Service Incorporated, Adelaide, South Australia. Dr. Tran is an inventor of the subject matter described and claimed in the present patent application and submits this Declaration in support of the position that none of the references teach or suggest that N-acetyl cysteine would enhance the anti-bacterial nature of hyperimmune colostrums or hyperimmune milk.

In this Declaration, the inventor points out that in Example 6 in the present invention it appeared that N-acetyl cysteine alone had no effect on bacterial colonization but did appear to have a significant effect in combination with hyperimmune colostrum. In contrast, there appeared to be less of an effect on bacterial colonization with non-hyperimmune colostrum.

As attested to in the attached Declaration, this finding was unexpected as the inventor did not expect to find significant enhancement of the inhibitory effect of the hyperimmune colostrums on bacterial colonization in the presence of a mucolytic agent, such as N-acetyl cysteine. In support of this unexpected finding, the inventor points to the fact that N-acetyl cysteine, as an example of a mucolytic agent, was expected to work to dissolve thick mucous by hydrolyzing glycosaminoglycans. In contrast to this expected reaction, the N-acetyl cysteine of the present invention actually appears to have unexpectedly formed a synergy with the lactoferrin to increase the reduction in bacterial colonization over the reduction seen with hyperimmune colostrum alone.

Applicant respectfully submits that a *prima facie* case of obviousness has not been made by the Examiner for any of the independent claims as none of the references teach or suggest the combined administration of N-acetyl cysteine and hyperimmune colostrums for an improved inhibition of bacterial colonization of mucous epithelium over hyperimmune colostrums alone. All other rejected claims depend from such independent claims. As such, the Examiner has not overcome the burden as required for him to make an obviousness rejection as the cited references do not alone or in combination teach each and every element of the claimed invention as the claim elements of each of the independent claims have not been addressed.

In view of the foregoing, Applicant respectfully requests withdrawal of the Examiner's rejection of claims 1-4, 6-12, 37-41, 43-50, 52-57 and 59-60 under 35 U.S.C. 103(a).

Concluding Comments

In view of the foregoing, Applicant respectfully submits that all claims are in condition for allowance. In the event the Examiner has any questions regarding the Applicant's position, a telephone call to the undersigned representative is requested.

Respectfully submitted,

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Date



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